Journal of Pharmaceutical and Biological Research
ISSN: 2347-8330 | https://doi.org/10.30904/j.jpbr.2026.4982

Development and Evaluation of Fast Dissolving Tablets of Pravastatin by Enhancing Dissolution Rate and Bioavailability

Golanukonda Sowjanya*, K. Nagasree, P. Laxmi, K. Shravan Kumar

Samskruti College of Pharmacy, Kondapur, Ghatkesar, Medchal, Hyderabad-501301, Telangana, India
***Corresponding E-Mail:** principal.y7@gmail.com*

Received: 23-02- 2026 | Revised: 12-03- 2026 | Accepted: 25-04- 2026 | Published: 14-05-2026

ABSTRACT
Pravastatin orally disintegrating films were successfully formulated using HPMC E15CPS and combinations of HPMC E15 and HPMC E5 polymers. Visual inspection and tactile evaluation revealed that the films possessed a smooth surface and were visually appealing. The film thickness ranged between 0.234 mm and 0.271 mm, with weight variation within ±10%. Folding endurance values ranged from 38 ± 1 to 57 ± 2, indicating good flexibility. Surface pH measurements showed neutrality with no color change on litmus paper, ensuring suitability for oral administration. Drug content uniformity tests demonstrated consistent drug loading, ranging from 98% to 102%. The films exhibited rapid disintegration times between 21 and 32 seconds. Among all batches, formulation F-9 displayed optimal mechanical properties and an in vitro disintegration time under 27 seconds, making it the most suitable formulation. Overall, formulation F-9 met the desired criteria and was selected as the optimized batch for further evaluation. This study confirms the potential of these orally disintegrating films as effective delivery systems for Pravastatin, combining acceptable mechanical strength, uniform drug distribution, and rapid disintegration for enhanced patient compliance.

Keywords: HPMC E15, HPMC E5, rapid disintegration, mechanical properties, drug content uniformity, film thickness

Introduction

Description:
Pravastatin, a benzisoxazole derivative, is an atypical antipsychotic drug with high affinity for 5-hydrotryptamine (5-HT) and dopamine D2 receptors. It is used primarily in the management of schizophrenia, inappropriate behavior in severe dementia and manic episodes associated with bipolar I disorder. Pravastatin is effective for treating the positive and negative symptoms of schizophrenia owing to its affinity for its "loose" binding affinity for dopamine D2 receptors and additional 5-HT antagonism compared to first generation antipsychotics, which are strong, non-specific dopamine D2 receptor antagonists.

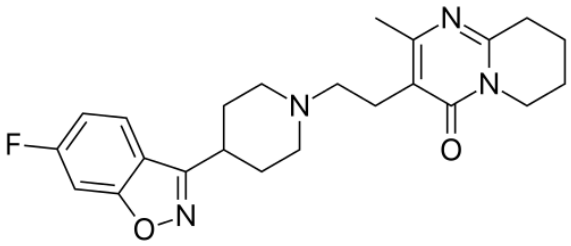

Fig.1: Structure of **P**ravastatin

Chemical Formula: $C_{23}H_{27}FN_4O_2$
IUPAC Name:
3-{2-[4-(6-fluoro-1,2-benzoxazol-3-yl)piperidin-1-yl]ethyl}-2-methyl-4H,6H,7H,8H,9H-pyrido[1,2-a]pyrimidin-4-one
Molecular Weight: 410.485 g/mol
Solubility: Pravastatin is soluble in organic solvents such as ethanol, DMSO, and dimethyl formamide (DMF), which should be purged with an inert gas. The solubility of Pravastatin in these solvents is approximately 0.3, 2, and 0.1 mg/ml, respectively. Pravastatin is sparingly soluble in aqueous buffers.
Melting Point: 170 °C
Indications:
For the treatment of schizophrenia in adults and in adolescents, ages 13 to 17, and for the short-term treatment of manic or mixed episodes of bipolar I disorder in children and adolescents ages 10 to 17. May also be used to manage symptoms of inappropriate behavior due to aggression and/or psychosis in patients with severe dementia.
Pharmacodynamics: Pravastatin is an atypical antipsychotic medication. It is most often used to treat delusional psychosis (including schizophrenia), but Pravastatin is also used to treat some forms of bipolar disorder and psychotic depression. It also has shown some success in treating symptoms of Asperger's Syndrome and autism. Pravastatin is now the most commonly prescribed antipsychotic medication in the United States.
Mechanism of action:
Blockade of dopaminergic D2 receptors in the limbic system alleviates positive symptoms of schizophrenia such as hallucinations, delusions, and erratic behavior and speech. Blockade of serotonergic 5-HT_2 receptors in the mesocortical tract, causes an excess of dopamine and an increase in dopamine transmission, resulting in an increase in dopamine transmission and an elimination of core negative symptoms. Dopamine receptors in the nigrostriatal pathway are not affected by Pravastatin and extrapyramidal effects are avoided. Like other 5-HT_2 antagonists, Pravastatin also binds at alpha(1)-adrenergic receptors and, to a lesser extent, at histamine H1 and alpha(2)-adrenergic receptors.

Materials and Methods

Table 1: List of materials used

S. No.	Materials	Source
1.	Pravastatin	Pharmatrain, Hyderabad
2.	HPMC E15	S.D. Fine chemicals, Mumbai
3.	HPMC E5	S.D. Fine chemicals, Mumbai
4.	Propylene glycol	S.D. Fine chemicals, Mumbai
5.	Sorbitol	S.D. Fine chemicals, Mumbai
6.	Aspartame	S.D. Fine chemicals, Mumbai
7.	Tween 80	S.D. Fine chemicals, Mumbai
8.	citric acid	S.D. Fine chemicals, Mumbai
9.	Flavouring agent	S.D. Fine chemicals, Mumbai

Table 2: List of Equipment's used

S.NO	Equipment's	Manufacturer/Supplier
1.	Electronic Balance module-AUW 2200	Shimadzu Corporation, Japan
2.	pH Meter	Metler Toledo, India
3.	UV-Visible Spectrophotometer	Labindia 3000+
4.	FT-IR Spectrophotometer 8300	Shimadzu-Corporation, Japan
5.	Humidity chamber	Thermo lab
6.	Dissolution Apparatus TDT-08L,	Electro lab, India.
7.	Filter (0.22µm)	Millipore, UK
8.	Vernier Caliper	Mitutoyo, Corps, Japan
9.	Disintegration tester (USP)	Electro Lab, India
10.	Hot air oven	Servewell instruments
11.	Sonicator	Sidilusonicator
12.	Gyratory shaker	Lab india.

Determination of λ_{max} of Pravastatin in 6.8 phosphate buffer:

Working standard:

50mg of Pravastatin was weighed and dissolved in 50ml 6.8 phosphate buffer and then made up to a volume of 50ml with 6.8 phosphate buffer it give 1000µg/ml ppm concentrated stock solution.

Dilution 1: From the working standard solution 10ml was diluted to 100ml with 6.8 phosphate buffer it will give 100µg/ml concentrated solution.

Dilution 2: From the working standard solution 10ml was diluted to 100ml with 6.8 phosphate buffer it will give 10µg/ml concentrated solution. This solution was scanned at range of 200-400nm wavelength light corresponding scan spectrum curve was noted .the corresponding wavelength having highest absorbance is noted as $\lambda_{max.}$

Construction of calibration curve of Pravastatin 6.8 phosphate buffer:

Procedure:

Working standard:

50mg of Pravastatin was weighed and dissolved in 50ml 6.8 phosphate buffer and then made up to a volume of 50ml with 6.8 phosphate buffer it give 1000µg/ml concentrated stock solution.

Dilution 1: From the working standard solution 10ml was diluted to 100ml with 6.8 phosphate buffer it will give 100 µg/ml concentrated solution. From dilution 1, take 0.5, 1, 1.5, 2 and 2.5ml of solution and was diluted up to mark in 10ml volumetric flask to obtain 5, 10, 15, 20 and 25µg/ml concentrated solutions. This solutions absorbance was noted at $\lambda_{max=280}$

Solubility determination:

Solubility of drug was determined by saturation solubility method. In this an excess amount of drug was added to 25ml of water and placed on a gyratory shaker for 24hr. Then solution was filtered and diluted with water. Absorbance of this sample was found by UV-spectrophotometer and results are interpreted in terms of solubility.

Photostability studies:

Normally 10 ml of fresh transparent glass vials with plastic caps were used for compatibility study. The drug is mixed with other excipients in the ratio of 1:1 and exposed to sunlight for a period of 1 month.

Fourier transform infrared radiation:

The infrared absorption spectra of pure drug, pure polymer and physical mixture of polymer and drug were performed for polymer drug interaction studies between 4000$cm^{-1}$to 400cm^{-1} by KBr pellet method.

Formulation of Pravastatin disintegrating films:

Preparation of mouth dissolving film by solvent casting method: An aqueous solution of the polymers was prepared using distilled water. Pravastatin was then added to this polymeric solution, followed by the incorporation of plasticizers such as propylene glycol. Additionally, a sweetener (aspartame) and peppermint flavor were included in the mixture. The resulting solution was cast onto a 9 cm diameter petri dish and left to dry at room temperature for 24 hours. After drying, the film was carefully peeled off from the petri dish, inspected for any defects, and cut into strips measuring 2 × 2 cm^2, each containing the equivalent dose. The cut films were stored in a desiccator at a relative humidity of 30-35% until further testing. This method mirrors typical solvent casting approaches for oral or transdermal film formulations where polymers, drug, plasticizers, sweeteners, and flavors are dissolved or dispersed, cast, dried, and cut for dosing.

Formulaton of Pravastatin fast dissolving films:

The mouth dissolving film of Pravastatin was prepared using the solvent casting technique. Initially, Solution 'A' was made by dissolving HPMC-E15 polymer in 5 ml of water. Separately, Solution 'B' was prepared by dissolving Pravastatin, Aspartame, Sorbitol, and citric acid in 5 ml of ethanol. Solutions 'A' and 'B' were then combined and stirred for 30 minutes. Propylene glycol, Tween 80, and a flavoring agent were added afterward, and stirring continued for an additional 10 minutes. The resulting mixture was cast onto a 9 cm diameter glass petri plate and dried in an oven at 70°C until a peelable film formed. The dried film was cut into rectangular pieces measuring 4 cm^2 (2 cm × 2 cm), each containing a dose of 10 mg of Pravastatin. Let me know if you need this in a more formal or detailed protocol style for documentation. The mouth dissolving film of Pravastatin was prepared by solvent casting. Solution 'A' was formed by dissolving HPMC-E15 polymer in 5 ml of water. Solution 'B' was prepared by dissolving Pravastatin, Aspartame, Sorbitol, and citric acid in 5 ml of ethanol. Both solutions were mixed together and stirred for 30 minutes. Then propylene glycol, Tween 80, and a flavoring agent were added, with stirring continued for 10 more minutes. The mixture was poured onto a 9 cm diameter glass petri dish and dried in an oven at 70°C until a peelable film was formed. The dried film was cut into 4 cm^2 (2 cm × 2 cm) rectangular pieces, containing 10 mg of Pravastatin per piece.

In vitro dissolution studies:

Using a European Pharmacopoeia paddle dissolution apparatus with 900 ml phosphate buffer (pH 6.8) at 37±0.5°C and 50 rpm, one film per test was dissolved. Samples of 5 ml were withdrawn at timed intervals, replaced with fresh medium, and drug release was analyzed by UV spectrophotometry at 280 nm. Cumulative percent drug release was plotted versus time.

In vitro release kinetics:

Drug release mechanisms from immediate-release dosage forms were analysed by fitting release data to zero-order or first-order kinetic models to describe the release rate.

A. Zero Order Release Kinetics:

It defines a linear relationship between the fractions of drug released versus time.

$$Q=k_0t$$

Where, Q is the fraction of drug released at time t and ko is the zero order release rate constant. A plot of the fraction of drug released against time will be linear if the release obeys zero order release kinetics.

The first-order release kinetics

The first-order release kinetics, as described by Wagner, assumes that the tablet's exposed surface area decreases exponentially during the dissolution process. According to this model, drug release from most sustained-release pellets follows first-order kinetics. The equation representing first-order kinetics is:

$$\log C = \log C_0 - kt \quad 2.303 \log C = \log C_0 - 2.303kt$$

Where CC is the amount of drug dissolved at time tt, C0C0 is the initial amount of drug dissolved at t=0t=0, and kk is the first-order rate constant. A plot of the logarithm of the percentage of drug remaining versus time produces a straight line if the drug release follows first-order kinetics.

Fourier Transform Infrared

Fourier Transform Infrared (FT-IR) Spectroscopy was used to analyze the interaction between the drug and the carrier. Samples were prepared by compressing them into potassium bromide (KBr) discs using a hydrostatic press. FT-IR spectra were recorded using a Thermo Electron FTIR spectrometer over a scanning range of 400 to 4000cm^{-1} with a resolution of 4 cm^{-1}. This technique helps in identifying and quantifying interactions between the pure drug and the optimized formulation components.

Results and Discussion

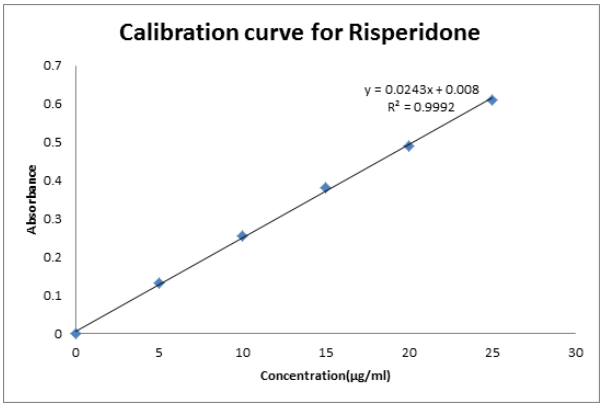

Fig.2: Standard calibration curve of Pravastatin in 6.8 phosphate buffer

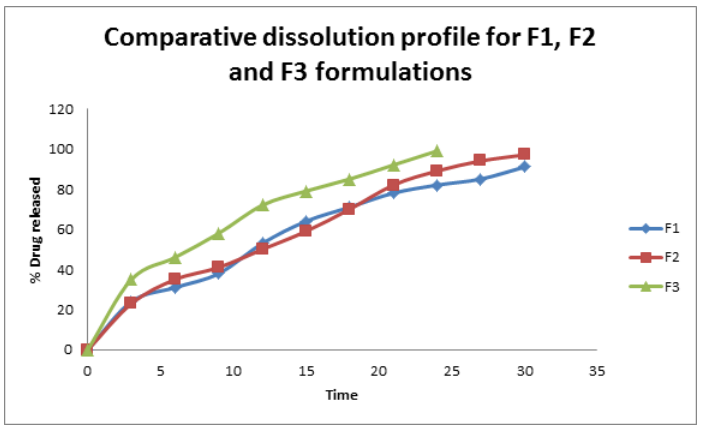

Fig.3: Dissolution profile for F1, F2 and F3 formulations

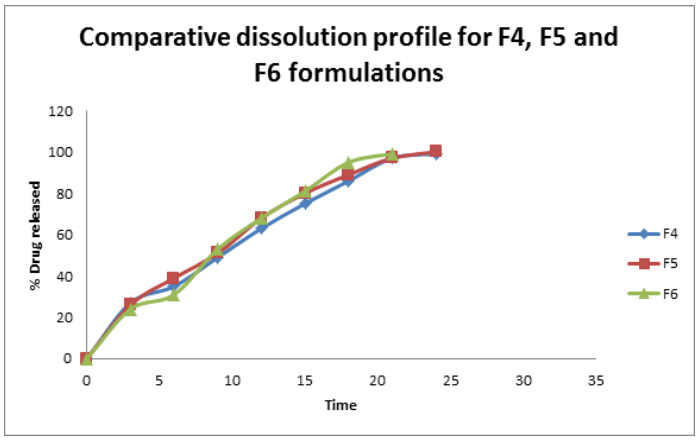

Fig.4: Dissolution profile for F4, F5 and F6 formulations

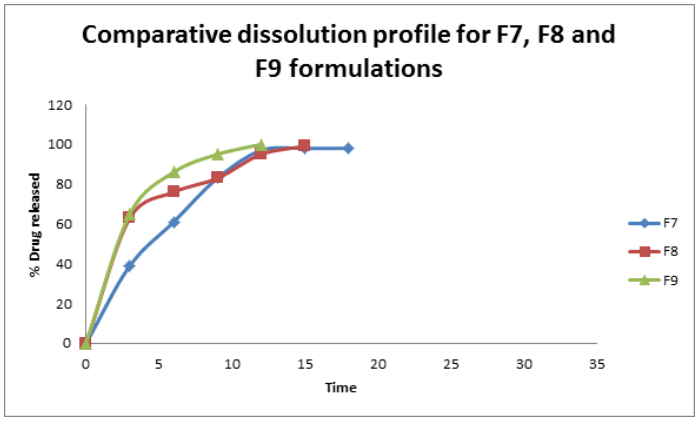

Fig.5: Dissolution profile for F7, F8 and F9 formulations

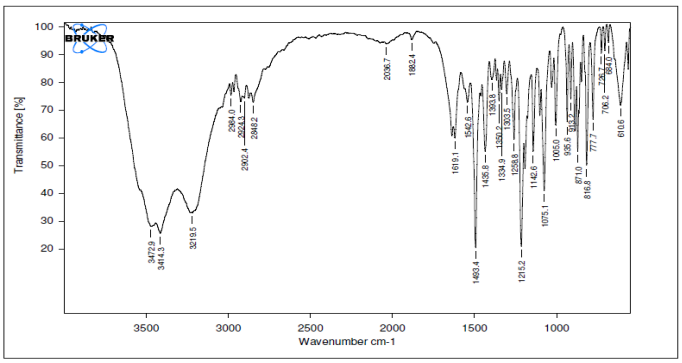

Fig.6: FTIR graph for Pravastatin

Table.3: Evaluation parameters of *Pravastatin* FDF

Formulation code	Appearance	Thickness (mm)	Weight variation	Folding endurance	% Assay	Dintegration time(sec)
F1	Smooth and Transparent	0.234	87	42	99.13	19
F2	Smooth and Transparent	0.271	91	51	98.79	24
F3	Smooth and Transparent	0.263	83	38	99.82	21
F4	Smooth and Transparent	0.247	85	57	100.17	27
F5	Smooth and Transparent	0.257	87	54	99.48	32
F6	Smooth and Transparent	0.234	90	49	101.07	28
F7	Smooth and Transparent	0.238	86	45	100.29	26
F8	Smooth and Transparent	0.265	91	39	99.37	23
F9	Smooth and Transparent	0.268	87	48	100.53	27

Table 4: In-vitro drug release data of formulation F1 to F6

TIME (min)	% DRUG RELEASE								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	**0**
3	24	23	35	27	26	24	39	63	**65**
6	31	35	46	35	39	31	61	76	**86**
9	38	41	58	49	51	53	83	83	**95**
12	53	50	72	63	68	68	97	95	**100**
15	64	59	79	75	80	81	98	99	
18	71	70	85	86	89	95	98		
21	78	82	92	97	97	99			
24	82	89	99	99	100				
27	85	94							
30	91	97							

Conclusion

- Pravastatin orally disintegrating films were successfully prepared with HPMC E15CPS and HPMC E15 & HPMC E5 combination.
- The observation by visual inspection of films and by feel or touch, it explains that the films are having smooth surface and they are elegant enough to see.
- The thicknesses of the films were in the range of *0.234 m*m to 0.*271m*m. The weights of the films were found to be in the range of *±10%*.
- Folding endurance of the films was found to be in the range of *38± 1 to 57 ± 2*.
- The surface pHs of all the films were found to be neutral as there was no colour change in the litmus paper.
- The drug content uniformity is performed by taking three films in each formulation trial and the average drug content was calculated. And all the films were found to be 98 to 102.
- The disintegration time of the prepared films were in the range of 21sec to 32sec.
- Acceptable mechanical properties were obtained in the batch F-9 and the in - vitro disintegration time was below of 27 sec.
- It was concluded that formulations F-9 were found to be satisfactory batch and were optimized for the desirable properties.

Acknowledgment

The authors thank the, Samskruti College of Pharmacy, Hyderabad, Telangana, India for technical assistance and support.

Conflict of Interests

The authors declare no conflict of interest

Ethics Approval

Not applicable

Funding

This study received no specific funding from public, commercial, or not for profit funding agencies.

AI Tool Declaration

The authors declare that no AI and related tools are used to write the scientific content of this manuscript.

Data Availability

Data will be available on request

References

[1] Dixit R, Puthli S. Oral strip technology: Overvie w and future potential. J. ControRelease 2009; 139: 94-107.

[2] Arya A, Chandra A, Sharma V, Pathak K. Fast dissolvi ng oral films: An Innovative DrugDelivery system and Dosage form. Int. J. Chem. Tech. Res. 2010:2: 576-83.

[3] Mashru C, Sutariya V, Sankali M, Parikh P. Development and evaluation of fast dissolving film of salbutamol sulphate. Drug Dev. Ind. Pharm. 2005; 31: 25-34.

[4] Nishimura M, Matsuurab K, Tsukioka T, Yamashita H, Inagaki N, Sugiyama T, Itoh Y. In vitro & in vivo characteristics of prochlorperazine oral disintegrating film.International Journal of Pharmaceutics 2009 Oct 15; 398: 98–102.

[5] Zhang H, Zhang J, Streisand J.B. Oral mucosal drug delivery: clinical pharmaco-kinetic and therapeutic applications, Clin. Pharmacokinet.2002; 41 (9): 661-680.

[6] Frey P. .Film Strips and Pharmaceuticals,. Pharma. Mfg. & Packag. Sourcer, winter, 2006: 92.93.
[7] Barnhart SD, Sloboda MS. The Future of Dissolvable Films. Drug Delivery Technol.2007;7 (8): 34-37.
[8] Nataraj Palaniyappan, Eswari Nataraj, Ravisankar Mathesan. Headspace GC-FID Based Estimation of Ethanol content in Indomethacin Oral Suspension. Journal of Pharma Crea ons (JPC):2025:14(4):222-230.
[9] Nataraj Palaniyappan, Eswari Nataraj, M.Ravisankar. Sensitive Gas Chromatographic Method for Monitoring Ethylene Glycol and Diethylene Glycol Contamination in Pharmaceutical-Grade Sorbitol. Journal of Pharma Crea ons (JPC). 2025;14(4):217-221.
[10] Nataraj Palaniyappan, Eswari Nataraj, Pal M Thangamathesvaran, Ravisankar Mathesan. AI-Based Prediction of Particle Size-Dissolution Relationships in Solid and Suspension Dosage Forms. Int. j. adv. multidisc. Res. stud. 2025; 5(4):325-335.
[11] Meathrel B, Moritz C. Dissolvable Films and Their Potential in IVDs. IVD Technol.2007; 13 (9): 53-58.